

§ 170.425

been tested and certified which includes, at a minimum:

- (1) The vendor name (if applicable);
- (2) The date certified;
- (3) The product version;
- (4) The unique certification number or other specific product identification;
- (5) The clinical quality measures to which a Complete EHR or EHR Module has been tested and certified;
- (6) Where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary; and
- (7) Where applicable, the certification criterion or criteria to which each EHR Module has been tested and certified.

(i) Retain all records related to tests and certifications according to ISO/IEC Guide 65:1996 (incorporated by reference in §170.499) and ISO/IEC 17025:2005 (incorporated by reference in §170.499) for the duration of the temporary certification program and provide copies of the final results of all completed tests and certifications to ONC at the conclusion of testing and certification activities under the temporary certification program;

(j) Promptly refund any and all fees received for:

(1) Requests for testing and certification that are withdrawn while its operations are suspended by the National Coordinator;

(2) Testing and certification that will not be completed as a result of its conduct; and

(3) Previous testing and certification that it performed if its conduct necessitates the recertification of Complete EHRs and/or EHR Modules;

(k) Ensure adherence to the following requirements when issuing a certification to Complete EHRs and/or EHR Modules:

(1) All certifications must require that a Complete EHR or EHR Module developer conspicuously include the following text on its Web site and in all marketing materials, communications statements, and other assertions related to the Complete EHR or EHR Module's certification:

(i) "This [Complete EHR or EHR Module] is 201[X]/201[X] compliant and has been certified by an ONC-ATCB in

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accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments."; and

(ii) The information an ONC-ATCB is required to report to the National Coordinator under paragraph (h) of this section for the specific Complete EHR or EHR Module at issue;

(2) A certification issued to an integrated bundle of EHR Modules shall be treated the same as a certification issued to a Complete EHR for the purposes of paragraph (k)(1) of this section except that it must also indicate each EHR Module that comprises the bundle; and

(3) A certification issued to a Complete EHR or EHR Module based on applicable certification criteria adopted by the Secretary at subpart C of this part must be separate and distinct from any other certification(s) based on other criteria or requirements.

§ 170.425 Application submission.

(a) An applicant for ONC-ATCB status must submit its application either electronically via e-mail (or web submission if available), or by regular or express mail.

(b) An application for ONC-ATCB status may be submitted to the National Coordinator at any time during the existence of the temporary certification program.

§ 170.430 Review of application.

(a) *Method of review and review timeframe.* (1) Applications will be reviewed in the order they are received.

(2) The National Coordinator will review Part 1 of the application in its entirety and determine whether Part 1 of the application is complete and satisfactory before proceeding to review Part 2 of the application in its entirety.

(3) The National Coordinator is permitted up to 30 days to review an application (submitted for the first time) upon receipt.

(b) *Application deficiencies.*

(1) If the National Coordinator identifies an area in an application that requires the applicant to clarify a statement or correct an error or omission, the National Coordinator may contact the applicant to make such clarification or correction without issuing a deficiency notice. If the National Coordinator has not received the requested information after five days, the applicant may be issued a deficiency notice specifying the error, omission, or deficient statement.

(2) If the National Coordinator determines that deficiencies in either part of the application exist, the National Coordinator will issue a deficiency notice to the applicant and return the application. The deficiency notice will identify the areas of the application that require additional information or correction.

(c) Revised application.

(1) An applicant is permitted to submit a revised application in response to a deficiency notice. An applicant may request an extension for good cause from the National Coordinator of the 15-day period provided in paragraph (c)(2) of this section to submit a revised application.

(2) In order to continue to be considered for ONC-ATCB status, an applicant's revised application must address the specified deficiencies and be received by the National Coordinator within 15 days of the applicant's receipt of the deficiency notice unless the National Coordinator grants an applicant's request for an extension of the 15-day period based on a finding of good cause. If a good cause extension is granted, then the revised application must be received by the end of the extension period.

(3) The National Coordinator is permitted up to 15 days to review a revised application once it has been received and may request clarification of statements and the correction of errors or omissions in a revised application during this time period.

(4) If the National Coordinator determines that a revised application still contains deficiencies, the applicant will be issued a denial notice indicating that the applicant will no longer be considered for authorization under the temporary certification program.

An applicant may request reconsideration of a denial in accordance with § 170.435.

(d) Satisfactory application. (1) An application will be deemed satisfactory if it meets all application requirements, including a passing score on the proficiency examination.

(2) The National Coordinator will notify the applicant's authorized representative of its satisfactory application and its successful achievement of ONC-ATCB status.

(3) Once notified by the National Coordinator of its successful achievement of ONC-ATCB status, the applicant may represent itself as an ONC-ATCB and begin testing and certifying Complete EHRs and/or EHR Modules consistent with its authorization.

§ 170.435 ONC-ATCB application reconsideration.

(a) An applicant may request that the National Coordinator reconsider a denial notice issued for each part of an application only if the applicant can demonstrate that clear, factual errors were made in the review of the applicable part of the application and that the errors' correction could lead to the applicant obtaining ONC-ATCB status.

(b) Submission requirement. An applicant is required to submit, within 15 days of receipt of a denial notice, a written statement to the National Coordinator contesting the decision to deny its application and explaining with sufficient documentation what factual errors it believes can account for the denial. If the National Coordinator does not receive the applicant's submission within the specified timeframe, its reconsideration request may be rejected.

(c) Reconsideration request review. If the National Coordinator receives a timely reconsideration request, the National Coordinator is permitted up to 15 days from the date of receipt to review the information submitted by the applicant and issue a decision.

(d) Decision. (1) If the National Coordinator determines that clear, factual errors were made during the review of the application and that correction of the errors would remove all identified deficiencies, the applicant's authorized representative will be notified of the